DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

November 14, 2014

Viora LTD.
Mr. Omri Kesler
Chief Operating Officer
3 Maskit Street
46733 Herzliya
Israel

Re: K142093
Trade/Device Name: V20 System
Regulation Number: 21 CFR 878.4810, 21 CFR 878.4400
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology, Electrosurgical cutting and coagulation device and accessories
Regulatory Class: Class II
Product Code: GEX, PBX
Dated: October 12, 2014
Received: October 16, 2014

Dear Mr. Kesler:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

David Krause -S

for Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K142093

Device Name
V20 system

Indications for Use *(Describe)*
The Viora V20 system is intended for dermatological procedures.

The V-ST Handpiece is indicated for the temporary relief of minor muscle aches and pain, temporary relief of muscle spasm, and temporary improvement of local blood circulation.

The V-IPL Handpiece with wavelengths 415-l200nm (with 5 different filters) is indicated for the treatment of:

- Moderate inflammatory acne vulgaris.
- Benign pigmented epidermal lesions including dyschromia, hyperpigmentation, melasma, and ephelides (freckles).
- Cutaneous lesions including warts, scars and striae.
- Benign cutaneous vascular lesions including port wine stains, hemangiomas, facial, truncal and leg telangiectasias, rosacea, erythema of rosacea, angiomas and spider angiomas, poikiloderma of Civatte and venous malformations.
- Removal unwanted hair. It is also intended for permanent reduction in unwanted hair. Permanent hair reduction is defined as the long-term stable reduction in the number of hairs regrowing when measured at 6, 9, and 12 months after the completion of a treatment regimen.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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510(k) Summary

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of the Safe Medical Devices Act of 1990 and 21 CFR 807.92.

Submitter Name and Address:	Viora Ltd. 3 Maskit Street Herzliya, Israel 46733 Israel
Contact Person:	Omri Kesler COO Email: omri@vioramed.com Phone Number: +972 9955 1344 Fax Number: +972 9955 1345
Establishment Registration Number:	3005695724
Date Prepared:	July 29, 2014
Device Trade Name(s):	**V20 system**
Device Common Name:	Multi application RF and IPL device
Classification:	**Name:** Laser surgical instrument for use in general and plastic surgery and in dermatology and Electrosurgical cutting and coagulation device and accessories. **Product code:** GEX, PBX **Regulation No:** 21 CFR878.4810, 21CFR878.4400 **Class:** II **Panel:** General and plastic surgery devices
Predicate Device(s):	Viora V-total™ (K133837)

Device description

The Viora ***V20 system*** is a RF and IPL multi application platform with two available treatment Handpieces:

V-ST Handpiece: Bi polar radiofrequency (RF) Handpieces

V-IPL Handpiece: Intense Pulsed Light (IPL) Handpiece

The Main Unit (console) provides the operational and safety function of the system. The operator can modify the treatment parameters to achieve specific tissue effects depending on individual patient's skin condition and anatomical structure. The Foot Switch is used for system activation.

Intended use and indication for use statement

The Viora V20 system is intended for dermatological procedures.

The V-ST Handpiece is indicated for the temporary relief of minor muscle aches and pain, temporary relief of muscle spasm, and temporary improvement of local blood circulation.

The V-IPL Handpiece with wavelengths 415-l200nm (with 5 different filters) is indicated for the treatment of:

- Moderate inflammatory acne vulgaris.
- Benign pigmented epidermal lesions including dyschromia, hyperpigmentation, melasma, and ephelides (freckles).
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- Removal unwanted hair. It is also intended for permanent reduction in unwanted hair. Permanent hair reduction is defined as the long-term stable reduction in the number of hairs regrowing when measured at 6, 9, and 12 months after the completion of a treatment regimen.

Predicade Devices

Substantial equivalence to the following predicate device is claimed:

Device Name	**510k No.**	**Date of Clearance**
Viora V-total™	K133837	April 9, 2014

Substantial Equivalence to Predicate Device

The ***V20 system*** and its predicate have the same intended use and the same indications for use (for the ST and IPL Handpieces). Furthermore, the ***V20 system*** and the predicate device have similar technological features. The Viora V20 V-ST and V-IPL Handpieces are exactly the same as the cleared Viora V-total ST and IPL Handpieces (k133837).

Any differences in the software and in the system design do not raise any new issues of safety and effectiveness, as was verified by performance testing.

Therefore, the ***V20 system*** is substantially equivalent to its predicate device.

Performance standards

The ***V20 system*** complies with:

- **IEC 60601-1**: Medical Electrical Equipment - Part 1: General Requirements For Basic Safety And Essential Performance.
- **IEC 60601-1-2**: Medical Electrical Equipment - Part 1-2: General Requirements For Basic Safety And Essential Performance - Collateral Standard: Electromagnetic Compatibility – Requirements And Tests.
- **IEC 60601-2-2:** Medical Electrical Equipment - Part 2-2: Particular Requirements For The Basic Safety And Essential Performance Of High Frequency Surgical Equipment And High Frequency Surgical Accessories.
- **IEC 60601-2-57:** Particular Requirements For The Basic Safety And Essential Performance Of Non-Laser Light Source Equipment Intended For Therapeutic, Diagnostic, Monitoring And Cosmetic/Aesthetic Use.

Performance Bench Tests

Bench testing demonstrated that the ***V20 system*** is as safe and effective as the cleared predicate devices.

Pre-Clinical and clinical study

Since the technological parameters of the Viora ***V20 system*** are well within the previously cleared Viora V-total system, Viora believes that animal and clinical studies are not required to determine the safety and efficacy of the ***V20 system.***

Conclusion

Based on the technological characteristics of the devices and the intended use, Viora believes that the ***V20 system*** and the predicate device are substantially equivalent. The differences do not raise any new issues of safety or effectiveness.